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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,040	07/24/2003	Michael Lebner	0156-2008US01	1249
7590 Kevin M. Farrell Suite 350 One New Hampshire Avenue Portsmouth, NH 03801			EXAMINER LEWIS, KIM M	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 05/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/626,040

Applicant(s)

LEBNER, MICHAEL

Examiner

Kim M. Lewis

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3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10, 22-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/15/07</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> .                  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/07 has been entered.
2. As requested, claims 1, 3, 20 and 22 have been amended. Claims 1, 3-20 and 22-38 are pending.

### ***Information Disclosure Statement***

3. The supplemental information disclosure statement filed 3/15/07 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 3, 4, 6, 10-12, 18, 19, 20, 22, 23, 25, 29-31, 33, 37 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,329,564 ("Lebner").

As regards claims 1 and 3, Lebner discloses a bandage for wound or incision closure that anticipates applicant's invention. More specifically, Lebner discloses a two-component device (1) for closing a laceration or incision, comprising: a) a first component (50) comprising a first adhesive-backed anchoring member, the first component being produced from a material having a degree of elasticity thereby providing improved adhesion relative to an otherwise identical first component produced from an inelastic material while maintaining the physical relationship between wound edges in an applied device for a period of time sufficient for the laceration or incision to heal naturally which is produced from a first polymeric material, b) one or more first connecting members (15), produced from a substantially inelastic material, attached to the first adhesive-backed anchoring member and extending from one edge thereof in a first direction, the one or more first connecting members being produced from a second polymeric material, c) a second component (25) comprising a second adhesive-backed anchoring member, the second component being produced from a material having a degree of elasticity thereby providing improved adhesion relative to an otherwise identical second component produced from an inelastic material while maintaining the physical relationship between wound edges in an applied device for the period of time sufficient for the laceration or incision to heal naturally which is produced from the first polymeric material; d) one or more second connecting members (35), produced from a substantially inelastic material, attached to the second adhesive-backed anchoring

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member and extending from one edge thereof in a second direction generally opposite to the first direction, the one or more second connecting members being produced by adhesive means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members (col. 1, line 66-col. 2, line 2).

Applicant is reminded of col. 2, lines 60-66 of the Lebner patent, which recites the following:

"In preferred embodiments, the flat flexible components, elongated connectors, and pulling elements described in the preceding paragraph are produced from a substantially inelastic polymeric material. Alternatively, they may be produced from an elastic material which is reinforced with an inelastic structural component thereby rendering the device substantially inelastic."

Thus, Lebner discloses that the components, connectors, and pulling elements may be constructed from elastic material reinforced with an inelastic structural component.

Thereby disclosing **both** elastic and inelastic material used as the material of construction for the components and the connectors.

As regards claim 4, note pulling elements (40, 45) and col. 5, lines 58-64.

Regarding claim 6, Lebner discloses that the pulling element and extensions of the connecting members are removable at the perforations (17, 37) following application of the device. The applicant should note that the extension of the connecting members

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is defined as the portion of the connecting member severed with pulling elements (40, 45).

Regarding claim 10, Lebner discloses that the device is constructed from a vapor-permeable (i.e., allow for the exchange of air) material (col. 3, lines 5-15).

Regarding claim 11, note col. 1, lines 43-46 and col. 1, line 66-col. 2, line 2, which disclose adhesive means.

Regarding claims 12 and 14, in col. 1, lines 48-65, Lebner discloses that both the anchoring members and the connecting members are protected by release liners, and that the first and second anchoring members are protected by first and second release liners (col. 1, lines 48-65).

Regarding claims 18 and 19, note the disclosure of reinforcements at col. 2, lines 60- col. 3, line 4.

Regarding claim 20, mere use of the modified device of discussed above in the rejection of claim 1 above obviates the claimed invention. The applicant should note that manipulating the pulling elements for attachment onto the anchoring member such that the wound or laceration is closed, necessarily involves adjusting the position of anchoring members in both an x and y dimension.

Regarding claim 22, Lebner discloses that the components, connectors, and pulling elements may be constructed from elastic material reinforced with an inelastic structural component. Thereby disclosing **both** elastic and inelastic material used as the material of construction for the components and the connectors.

Regarding claims 23, 25, 29-31, 33, 37 and 38, note the rejection of claims 4, 6, 10-12, 14, 18 and 19, respectively.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5, 7-9, 13, 15-17, 24, 26-28, 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebner.

Regarding claims 5 and 7-9, Lebner fails to teach that the pulling elements are coded to enable user distinction, that the coding comprises an observable geometric distinction between the shape of the pulling elements and the shape of the anchoring members, that the coding comprises printed indicia enabling user distinction between pulling elements and anchoring members, that the coding on the pulling elements distinguishing colors, or that the anchoring members are provided with one or more alignment indicators. However, Lebner discloses at col. 4, lines 38-53, that the bandage can include wound closure visual alignment indicators, and further discloses at col. 5, lines 1-21, that the bandage can include indicia (e.g., color, graphic representations, etc.) for the purpose of indicating specific information to the user (e.g., tension). In light of these disclosures, it would have been prima facie obvious to one having ordinary skill in that art at the time of invention to provide any portion of the Lebner bandage with



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indicia of various types (e.g., colors, shapes, printed material, etc.) in order to indicate any information.

Regarding claims 13 and 15-17, note the rejection of claims 5 and 7-9 above. The same rationale applies to claims 13 and 15-17. As such, the claims are not distinguishable over the prior art.

Regarding claims 24, 26-28, 32, and 34-36, note the rejection of claims 5, 7-9, 13 and 15-17 above.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Monday to Friday, from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kim M. Lewis  
Primary Examiner  
Art Unit 3772

kml  
May 22, 2007